K081287

Den-Mat® Holdings, LLC
ISO 9001 Certified
2727 Skyway Drive
Santa Maria, CA 93455
Phone: (805) 922-8491
FAX: (805) 922-6933

NOV 21 2008

510(k) Summary Statement for the Sapphire®
Supreme Plasma Arc Dental Curing Light

The following Summary has been prepared pursuant to requirements listed in 21CFR 807.92(a)

1. Owner

Den-Mat Holdings, LLC.

2727 Skyway Drive

Santa Maria, CA 93455 USA

Contact Person: Alan Matthews

Telephone: 805-922-8491

FAX: 805-922-6933

Date Prepared: 30 April 2008

2. Device Name

Proprietary Name: Sapphire® Supreme PAC Dental Curing Light

Common Name: dental curing light

Classification Name: ultraviolet activator for polymerization (21 CFR 872.6070),

product classification code EBZ

3. Predicate Device

PlasmaCure BXe (K033795) eeLe Laboratories, LLC, Bohemia, NY 11716 USA

4. Device Description

The Sapphire Supreme Plasma Arc Dental Curing Light consists of a xenon plasma arc light source (lamp), power supply with user interface controls, and a light guide with a pistol-type handpiece with user interface controls. The light from the xenon arc lamp is transmitted through optical filters that largely eliminate unnecessary ultraviolet (UV), visible, and infrared (IR) wavelengths into the proximal end of the light guide, where it is conducted

through a fiber-optic bundle and focused through a removable tip at the distal end of the light guide. Controls on both the light source and the handpiece activate the lamp and time of exposure.

The Sapphire PAC Light safely and effectively transmits blue light at wavelengths and with sufficient intensity to initiate photopolymerization of light-cured dental restorative materials. Ultraviolet (UV) and infrared (IR) blocking filters are placed between the xenon arc lamp and the light guide. The wavelength of the blue light transmitted by the device is chosen to cure all common dental photoinitiators; its irradiant intensity is powerful enough to initiate rapid polymerization while not so strong as to be a thermal hazard.

5. Intended Use

The Sapphire PAC Light is a source of illumination for curing dental restorative materials and is a source of illumination for tooth whitening activities performed in dentistry.

6. Technological Characteristics and Substantial Equivalence

The technological and operational principles of both the proposed and predicate devices are identical. Both transmit visible blue light at wave lengths known to initiate photopolymerization of common dental photoinitiators. Both devices use xenon arc lamps as the source of illumination; however, the predicate device' handpiece houses the lamp and filter assembly whereas the proposed device' lamp and filter assembly is housed in a base unit and uses a fiber-optic bundle to transmit light to the light-cured restorative material. Both devices employ removable curing tips to focus radiant energy and permit unit sanitization between patients. Both devices' time of exposure can be controlled from the handpiece; the proposed device may also be controlled via controls on the base unit.

7. Performance Testing

The proposed device has been found to conform to the requirements in ANSI/ADA Specification No. 48, Visible Light Curing Units (2004), and to normalized standards for electromagnetic compatibility and safety characteristics of medical equipment.

Conclusion

Testing confirms that the proposed Sapphire Supreme PAC Light is safe and effective for its intended use as a dental curing light and as a source of illumination for dental tooth-whitening activities.. The subject device is substantially equivalent to the predicate device in regard to its intended use, characteristics, performance, labeling, and safety features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Alan Matthews
Quality Assurance Manager
Den-Mat Holdings, L.L.C.
2727 Skyway Drive
Santa Maria, California 93455

NOV 21 2008

Re: K081287
Trade/Device Name: Sapphire Plasma Arc (PAC) Dental Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: October 30, 2008
Received: November 14, 2008

Dear Mr. Matthews:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5. **Indications for use**

510(k) Number (if known): K081287

Device Name: Sapphire Plasma Arc (PAC) Dental Curing Light

The Sapphire PAC Light is a source of illumination for curing dental restorative materials and is a source of illumination for tooth whitening activities performed in dentistry.

Prescription Use _x_ and/or OTC Use _____

(Per 21 CFR 801 subpart D) (Per 21 CFR 801 subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081287